

US EPA ARCHIVE DOCUMENT

**Session I**

**Registration Production Issues  
for Conventional and Biological Pesticides**

**July 21, 1999**

**Presentation to the Pesticide Program Dialogue Committee**

## OPP Resources Dedicated to the Registration Program

<b>Fiscal Year</b>	<b>FTE</b>	<b>Contract s</b>
<b>FY98</b>	<b>261.6</b>	<b>\$4,970K</b>
<b>FY99</b>	<b>270.7</b>	<b>\$4,054.5K</b>

The Registration Program is comprised of three regulatory areas:

- ! **Biological Pesticides**  
(Biochemicals, microbes both naturally and genetically-altered, and plant pesticides)
- ! **Antimicrobial Pesticides**
- ! **Conventional Pesticides**

## OPP Resources Dedicated to the Registration of Pesticides in FY99

**FTE:** 271 FTE are allocated for registration activities:

- ! Antimicrobial Registration Activities: 25 FTE
- ! Biopesticide Registration Activities: 40 FTE
- ! Conventional Chemical Registration Activities: 167 FTE
- ! Program Management and Support: 39 FTE

### **Contracts**

- ! 4,054.5K in contract dollars have been allocated for registration activities
- ! In April 1999, the Deputy Administrator allocated an additional \$1 million to the Registration Program to expedite reviews and decisions for reduced-risk pesticides.
- ! Total FY '99 contract dollars = \$5,054.5

## HISTORICAL COMPARISON OF NEW ACTIVE INGREDIENT REGISTRATIONS UNDER SECTION 3 OF FIFRA

Fiscal Year	Biologica ls	Conventionals		Antimicro bials	Total
		Regula r	Safer		
1988	2	10	0	1	13
1989	3	15	0	0	18
1990	1	5	0	0	6
1991	9	4	0	0	13
1992	6	7	0	1	14
1993	4	12	0	1	17
1994	15	10	2	4	31
1995	17	16	3	2	38
1996	10	6	3	3	22
1997	15	7	4	2	28
1998	12	11	2	2	27

<b>1999 to date</b>	<b>10</b>	<b>5</b>	<b>4</b>	<b>1</b>	<b>20</b>
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### Conventional Chemical Registration Program Activities

	<b>FY98 Comple tions</b>	<b>FY99 Comple tions (as of 6/30)</b>
<b>New Chemicals</b>	<b>13</b>	<b>9</b>
<b>Tolerances</b>	<b>239</b>	<b>181</b>
<b>Experimental Use Permits</b>	<b>10</b>	<b>11</b>
<b>New Uses for Existing Active Ingredients</b>	<b>144</b>	<b>70</b>
<b>Section 18 Emergency Exemption Requests</b>	<b>504</b>	<b>425</b>
<b>Average Processing Time for Section 18 Requests</b>	<b>56 days</b>	<b>59 days</b>
<b>Section 24(c) Special Local Needs Requests</b>	<b>455</b>	<b>335</b>
<b>Old Chemical Product Registrations (Fast Tracks and Non-Fast Tracks)</b>	<b>621</b>	<b>284</b>

Old Chemical Amendments (Fast Tracks and Non-Fast Tracks)		2,524	1,539
Inter ts	Food Use	14	3
	Non-Food Use	94	71
Notifications		1,810	1,218

## Biopesticide Registration Program Activities

	<b>FY98 Completi ons</b>	<b>FY99 Completi ons (as of 7/12)</b>
<b>New Active Ingredients</b>	<b>12</b>	<b>10</b>
<b>Tolerance Exemptions</b>	<b>13</b>	<b>10</b>
<b>New or added uses for existing active ingredients*</b>	<b>57</b>	<b>335</b>
<b>Experimental Use Permits</b>	<b>13 new 5 amendm ents</b>	<b>11 new 4 amendm ents</b>
<b>Section 24(c) Special Local Needs Requests</b>	<b>4</b>	<b>6</b>
<b>Existing Active Ingredient Product Registrations (Fast Tracks and Non-Fast Tracks)</b>	<b>47</b>	<b>71</b>
<b>Existing Active Ingredient Amendments (Fast Tracks and Non-Fast Tracks)</b>	<b>136</b>	<b>148</b>



Biotechnology Notifications for Field Trials of Genetically-Altered Microorganisms	3	1
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\*An added use requires no new data to be reviewed or a change in the tolerance (exemption). Biopesticide tolerance exemptions are often established for all food commodities and additional uses are added to pesticide labels at a later time.

## What's Currently Pending in the Conventional Chemical Pipeline (as of July 1, 1999)

- ! New active ingredients: 48
- ! New Food Uses: 455 (involving over 100 active ingredients)
- ! EUPs: 10

## What's In the Workplan for FY99

- ! New active ingredients: 20 candidates, covering 54 food uses and 4 non-food uses
  - RD goal for FY99 is to make decisions for 13 new chemicals
  - Through June 1999, we have registered 9 new chemicals (5 reduced-risk) and received 1 withdrawal
- ! New Food Uses: 120 new use candidates, covering 35 active ingredients
  - RD goal for FY99 is to make decisions for 57 new uses
  - Through June 1999, we've already issued 70 new use decisions
- ! EUPs: 1
  - At mid-year, we've issued the 1 EUP listed in the workplan
  - In addition, we've issued another 10 unscheduled EUPs

through June 1999.

## How Do We Prioritize the Pending Workload

- ! Methyl Bromide Alternatives
- ! OP Alternatives which are Reduced Risk Candidates
- ! Other Reduced Risk Candidates
- ! Non-reduced risk OP Alternatives
- ! USDA/EPA - vulnerable Crop / pest combinations
- ! IR-4 Petitions
- ! Minor Crop Uses Submitted by Registrants
- ! Trade irritants
- ! Other Registrant Identified Actions

Using this priority scheme as guidance, incorporating other identified critical needs, and identifying “low hanging fruit”, RD works with HED and EFED to cull together new chemical, new use, and EUP candidates for decision-making.

Typically, we identify several more candidates in each category than we expect to complete.